

REMARKS

All the claims submitted for examination in the parent application of the instantly filed RCE application were rejected on substantive grounds. Applicants have amended their claims and respectfully submit that the claims currently in this application are patentable over the rejection of record.

Applicants submit that the claims finally rejected in the parent of the present RCE application were patentable over the substantive rejection of record based on the arguments advanced in applicant's Amendment under 37 C.F.R. §1.116, filed January 15, 2004. However, in a spirit of cooperation, and to better emphasize the patentable nature of these claims, applicants have amended the broadest claim currently in this application, Claim 1, to incorporate therein the limitation of Claim 2. Thus, amended Claim 1 limits the claimed pharmaceutical composition to one in which the weight ratio of the R(+) enantiomer of amlodipine to the S(-) enantiomer of amlodipine is greater than 1:1 but less than 10:1.

The aforementioned amendment to Claim 1 makes Claim 2 redundant. Claim 2 has thus been cancelled.

Amended Claim 1 better emphasizes the saliency of the arguments for patentability, advanced in the Amendment under 37 C.F.R. §1.116, filed January 15, 2004, which will now be entered with the refiling of the instant RCE application.

The crux of the argument advanced in the aforementioned Amendment under 37 C.F.R. 1.116 lies in the novel weight ratio of R(+) to S(-) enantiomers of amlodipine. That weight ratio provides the optimal ratio of those enantiomers in providing treatment of stenosis or arteriosclerosis without unacceptable drop in blood pressure.

Stated differently, the recited weight ratio in Claim 1 represents a significant

improvement over a racemic mixture, which the earlier Amendment emphasizes represents a R(+) to S(-) enantiomer ratio of 1:1. This is so insofar as a racemic mixture imposes an unnecessarily low limit on the amount of R(+) enantiomer thus preventing as effective a treatment of stenosis or arteriosclerosis as can be provided.

As indicated at Page 5 of the specification, the optimal ratio of R(+) to S(-) enantiomers is about 5:1. No suggestion is made in any of the applied references, or for that matter in the prior art, of this optimal ratio. Nor is it known in the art to produce pharmaceutical compositions which encompass this ideal ratio of enantiomers. Furthermore, none of the references applied in the rejection of record suggest a pharmaceutical composition encompassing this ratio of enantiomers for the purpose of treating stenosis or arteriosclerosis.

It is apparent that the final rejection of the claims of the parent application of the present RCE application utilized the impermissible exercise of taking the present application as a template and identifying references that, employing a hindsight appreciation of the invention, met individual features of the claimed composition of the present application.

Applicants direct attention to the excellent discussion of Suggestion or Motivation to Modify References, set forth in the Manual of Patent Examining Procedure at §2143.01. That discussion, including the case law cited therein, emphasizes that in a case such as this, wherein there is no motivation suggested in the prior art to practice the claimed invention, a composition having the claimed ratio of amlodipine enantiomers, albeit it is within the skill of the prior art to combine the enantiomers in the ratio recited, there is no prima facie case of obviousness presented requiring a showing of unexpected results.

In summary, applicants submit that the arguments advanced in the Amendment under 37 C.F.R. §1.116, filed January 15, 2004, now of record in the file of the present application,

as well as the above amendment and remarks, establish the patentable nature of all the claims currently in this application. Notice of Allowance and passage to issue of these claims, Claims 1, 3-20, 29 and 33, is therefore respectfully solicited.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Marvin Bressler", with a long horizontal flourish extending to the right.

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